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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/922,066	08/03/2001	Thierry Godel	20706	8721

151 7590 01/29/2003

HOFFMANN-LA ROCHE INC.  
PATENT LAW DEPARTMENT  
340 KINGSLAND STREET  
NUTLEY, NJ 07110

EXAMINER
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PATEL, SUDHAKER B

ART UNIT	PAPER NUMBER
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1624

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DATE MAILED: 01/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/922,066

Applicant(s)  
Th. Godel et al

Examiner  
SUDHAKER PATEL, D.Sc.Tech.

Art Unit  
1624



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Mar 5, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-70 is/are pending in the application.
- 4a) Of the above, claim(s) 10-12, 16-34, 36-38, 46-49, and 53-66 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9, 13-15, 35, 39-45, 50-52, and 68-70 is/are rejected.
- 7) ☒ Claim(s) 67 is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some\* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4, 7 6) ☐ Other:

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## DETAILED ACTION

### I.

#### *Election/Restriction*

1. This application contains claims directed to the following patentably distinct species of the claimed invention: (1). The variable R1 = a) to n) which involve aryl, heterocycle or non-heteroaryl, non-aromatic heterocycle and many other groups.

(2). The variables R and R2, and R4 /R4' when form a fusion with the existing ring, will provide additional species.

(3). (1). And (20). Above when considered with variable X with further provide multiples of species which have different structures..

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 2, 68-70 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered /nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations

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of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

2. During a telephone conversation with Mr. A. D. Dowson on 1/14/02 a provisional election was made with traverse to Claims(in part) 1-9,13-15,35,39,40-43,44,45,50,51,52,68-70, prosecute the invention of species of Claim 4,8( = Example 1 )Claim 52 (Example 11).


Affirmation of this election must be made by applicant in replying to this Office action. Claims 10-12,16-18,19-20,21-34,36-38,46,47,48,49,53-66 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Since claims 1-9,13-15,35,39,40-43,44,45,50,51,52,68-70 link with other inventions, they will be examined bearing in mind the subject matter as elected by the applicants.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventor ship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventor ship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

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Applicants are reminded of the election of species guidelines provided in MPEP 803.02, which are followed for examination.

Initial search revealed prior art. As per the guide lines stated above, the search is limited to various variables having following values:

R1 = 6-membered non-aromatic heterocycle consisting of 2 heteroatoms which are (un)substituted by -C(O)(OR'); 

R7 = oxo;

N = 1 or 2;

R = H;

m = zero;

R2 = alkyl or halogen;

X = -CO-N(R8)-;

R3/R3' = H/ lower alkyl;

R4/R4' = H/CF3;

R/R2 or R4/R4' = open & not forming a fusion with the ring.

Therefore, claims 10-12,16-18,19-20,21-34,36-38,46,47,48,49,53-66 are withdrawn from further consideration as they constitute non-elected subject matter 37 CFR 1.142(b). All other definitions of variables R1 (= a) to l.), and R7, X are additionally withdrawn from further consideration.

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**II.** *Information Disclosure Statement*

Signed copies of the IDS papers # 4 and 7 PTO FORMS 1449 are enclosed with this Office Action for applicants' records.

**III.** *Claim Rejections - 35 U.S.C. § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b).

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Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims are rejected under 35 U.S.C. 102(e) as being anticipated by (I).U.S.P 6297 375 10/2/2001; filed as U.S. Sr. # 09507456 dated 2/22/2000; claiming priority to EP 99103504 filling date 2/24/1999(Note this ref. Is also cited as CAS Abstr. 133:207811-2000:607348 and also as DE 10008042 8/31/2000). See compounds recited as having CAS RN # 290296-83-2 = 1-piperazinecarboxylic acid,4-[5-[[[3,5-bis(trifluoromethyl)phenyl]methyl]methylamino]carboxyl]-4-(2-methylphenyl)-2-pyridinyl]-1,1-dimethylester. CAS RN # 290296-85-4 = 4-piperidine carboxylic acid, 1-[5-[[[3,5-bis(trifluoromethyl)phenyl]methyl]methylamino]carbonyl]-4-(2-methylphenyl)-2-pyridinyl)-ethyl ester. CAS RN # 290296-86-53-pyridinecarboxamide,N-[[3,5-bis(trifluoromethyl)phenyl]phenyl]methyl]-N-methyl-4-(2-methylphenyl)-6-(4-propyl-1-piperazinyl)-. CAS RN # 290296-87-6 = 3-pyridinecarboxamide, 6-[3-(acetylmethylamino)-1-pyrrolidinyl]-N-[[3,5-bis(trifluoromethyl)phenyl]methyl]-N-methyl-4-(2-methylphenyl)-.

The applied reference has a common inventor(s) and assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

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**IV.**

***Claim Objections***

Claim 67 as recited on page 67 is objected to because of the following informalities: It is recited as dependent on claim 67 i.e. itself. Therefore, this claim is also withdrawn from further consideration. See rejections bellow.

**V.**

***Claim Rejections - 35 U.S.C. § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9,13-15,35,39,40-43,44,45,50,51,52,68-70 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention.

Evidence that claim 67 fail(s) to correspond in scope with that which applicant(s) regard as the invention can not be found in claim 1 as filed.

Following additional reasons apply.

(A). In claim 1 R5 is recited as “ aryl,..substituted”. This is not acceptable because we are exactly and definitely not told about the make up under this term and the exact position(s) of substituents. See In re Sus et al., 135 USPQ 301; In re Lund et al, 153 USPQ 625, 134 USPQ 301.



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(B). In claims 1,2 7 applicants recite the term “ at least one”. This is indefinite because it also includes other possibilities. For the substituents. See *Petrolite Corp. Vs. Watson, Comr. Pats.*, 113 USPQ 248.

(C). In compound claim 8 one of the substituent is cited as “-6-(4-hydroxyacetyl) and in claim 1 R1 is defined in I). As having a substituent  $-(CH_2)_n$  OR’, and  $R' = H/OH/lower\ alkyl$ . Therefore, it is difficult to interpret substituent as  $-O-COCH_3$  as presented in the claim.

(D). Claims 69 and 70 recite “medicament..... at least one pharmaceutically acceptable excipient”. It is not very clear as to what applicants want to claim. Replacement by “ pharmaceutical composition ..... and a pharmaceutically acceptable carrier” is suggested.

(E). Claim 70 recited “treatment of diseases related to NK-1 receptor antagonists”. This is indefinite because it is not presenting a definite disease(s) but it also includes diseases yet to be discovered. Therefore, one of ordinary skill can not reproduce the claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sudhaker Patel,D.Sc.Tech. whose telephone number is (703) 308 4709.

The examiner can normally be reached on Monday thru’ Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by the phone are unsuccessful, the examiner’s supervisor, Dr.Mukund Shah can be reached at (703) 308 4716 or Sr. Examiner Mr. Richard Raymond at (703) 308 4523.

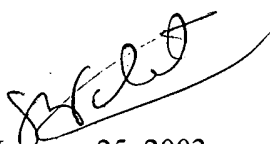
A facsimile center has been established for Group 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machine are (703) 308-4556 or (703) 305-3592.

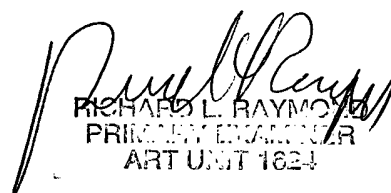
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Any inquiry of general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308 1235.

  
Sp/January 25, 2003.

  
RICHARD L. RAYMOND  
PRINCIPAL ENGINEER  
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